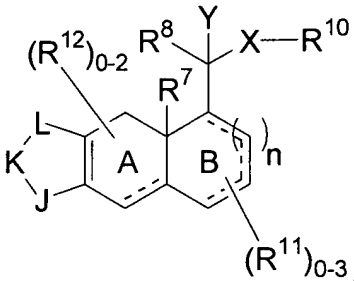
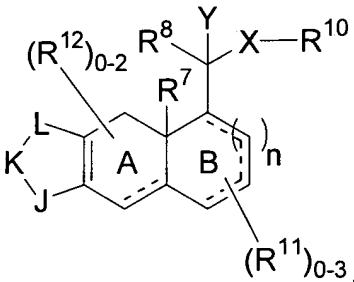


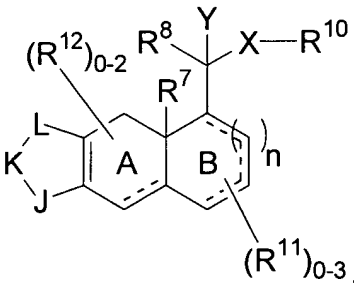
, wherein L is C(R^1)(R^2)[*sic*]; K is NR^3, J is NR^1; R^1 is phenyl group; R^1 is H [*sic*]; R^2 is H [*sic*]; R^8 is H; Y is OR^9; R^9 is H; n is 1; X is a bond and R^{10} is phenyl or naphthalene.

Group II: Claims 1-21 (in part), drawn to products of Formula I,



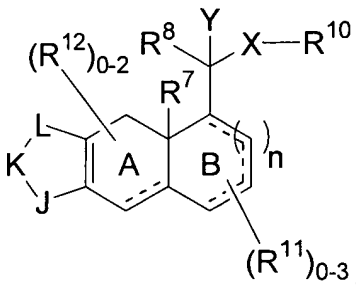
, wherein L is C(R^1)(R^2)[*sic*]; K is NR^3, J is NR^1; R^1 is phenyl group; R^1 is H[*sic*]; R^2 is H[*sic*]; R^8 is H; Y is OR^9; R^9 is H; n is 1; X is a bond and R^{10} is furanyl.

Group III: Claims 1-21 (in part), drawn to products of Formula I,



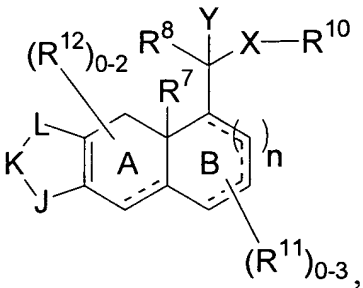
, wherein L is C(R^1)(R^2)[*sic*]; K is NR^3, J is NR^1; R^1 is phenyl group; R^1 is H[*sic*]; R^2 is H[*sic*]; R^8 is H; Y is OR^9; R^9 is H; n is 1; X is a bond and R^{10} is thienyl.

Group IV: Claims 1-21 (in part), drawn to products of Formula I,



, wherein L is C(R^1)(R^2)[*sic*]; K is NR^3, J is NR^1; R^1 is phenyl group; R^1 is H[*sic*]; R^2 is H[*sic*]; R^8 is H; Y is H; n is 1; X is N(R^{14})-C(O) and R^{10} is alkyl or cycloalkyl.

Group V: Claims 1-21 (in part), drawn to products of Formula I,



, containing compounds not encompassed in Groups I-IV and subject to further restriction, if elected.

Group VI: Claims 22-24 (in part), drawn to a method of treating leukemia, comprising administering a compound of Formula I, wherein L is C(R^1)(R^2)[*sic*]; K is NR^3, J is NR^1; R^1 is phenyl group; R^1 is H[*sic*]; R^2 is H[*sic*]; R^8 is H; Y is OR^9; R^9 is H; n is 1; X is a bond and R^{10} is phenyl or naphthalene.

Group VII: Claims 22-24 (in part), drawn to a method of treating stroke, comprising administering a compound of Formula I, wherein L is C(R^1)(R^2)[*sic*]; K is NR^3, J is NR^1; R^1 is phenyl group; R^1 is H[*sic*]; R^2 is H[*sic*]; R^8 is H; Y is OR^9; R^9 is H; n is 1; X is a bond and R^{10} is furanyl.

Group VIII: Claims 22-24 (in part), drawn to a method of treating pulmonary disease, comprising administering a compound of Formula I, wherein L is C(R^1)(R^2)[*sic*]; K is NR^3, J is NR^1; R^1 is phenyl group; R^1 is H[*sic*]; R^2 is H[*sic*]; R^8 is H; Y is OR^9; R^9 is H; n is 1; X is a bond and R^{10} is thienyl;

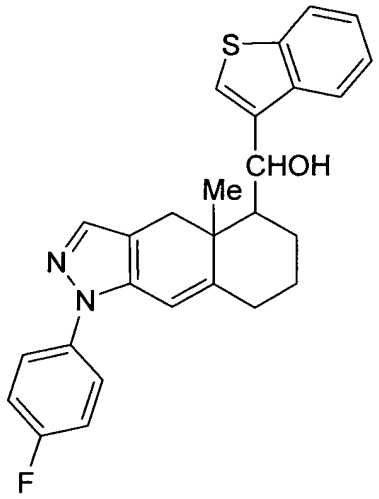
Group IX: Claims 22-24 (in part), drawn to a method of treating a disease other than those of Groups VI-VIII of Formula I, containing compounds not encompassed in Groups I-IV, subject to further restriction if elected.

The Examiner has indicated that the above is not an exhaustive list.

Group I is hereby elected with traverse. Applicants also hereby elect the specie of Example 35 (structure shown at page 58), with traverse. Inasmuch as the Examiner requires election of a single disease to be treated, Applicants elect rheumatic disorders, such as rheumatoid arthritis.

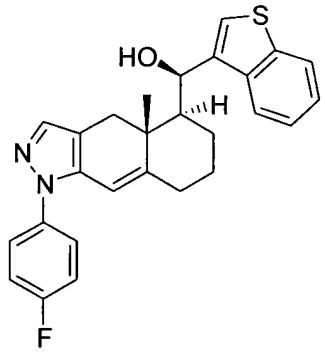
Applicants respectfully request reconsideration of the restriction requirement with respect to Claims 1 to 24 and submit that these claims satisfy the unity of invention requirement because the groups are properly linked to form a single general inventive concept. As outlined in M.P.E.P. § 1893.03(d), a group of inventions is considered linked to form a single general inventive concept when there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression "special technical feature" is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. In the instant claims, the special technical feature is the novel and non-obvious core structure embodied in Formula I. All compounds share this significant common chemical structure. The claimed compounds also possess the same utility as glucocorticoid receptor modulators and for treating diseases or conditions mediated by that receptor. As such, unity of invention is present.

In the Official Action, the Examiner states that the structural moiety common to **Groups I-IX** is Formula I. However, the Examiner alleges that this technical feature is not a special technical feature, because it fails to define a contribution over the prior art. In support thereof, the Examiner cites U.S. Patent No. 6,831,093 ("the '093 patent"), which discloses the species:

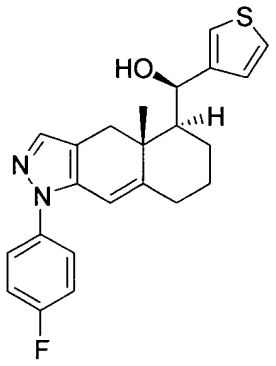


and which is claimed in instant Claim 17. The Examiner concludes that claims 1 to 24 therefore are not linked as to form a single general inventive concept and thus lack of unity of invention.

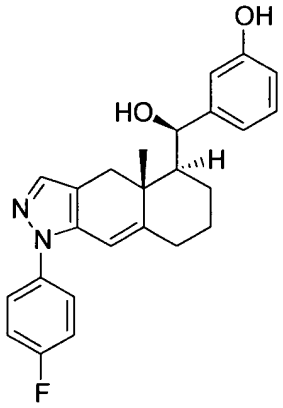
Applicants submit herewith a Declaration of Christopher F. Thompson showing invention of three species within the genus of Formula I prior to January 22, 2002, which is the effective date as a reference of the '093 patent under 35 U.S.C. § 102(e) for subject matter described in the first priority application. The three species are as follows:



EXAMPLE 39



EXAMPLE 42



EXAMPLE 70

These three species correspond to Examples 11, 18 and 14, respectively, as described in U.S. Serial No. 60/351,484, filed January 22, 2002. Applicants submit that the showing of prior completion of the above species by the Applicants put the Applicants in possession of the genus of Formula I prior the reference's date. Additional species within the genus of Formula I were completed prior to January 22, 2002 and can be provided if such information is required.

Based on the foregoing, Applicants submit that the '093 patent is not prior art to the genus of Formula I and as such, Applicants are not required to define a contribution over this reference for purposes of unity of invention. As a result, the Examiner has failed to establish that the structural moiety of Formula I does not make a contribution over the prior art. Unity of invention is therefore present.

The Examiner should note that the dates on the notebook pages attached to the Declaration of Christopher F. Thompson have been redacted. *See* M.P.E.P. § 715.07, Part II.

At page 6 of the Official Action, The Examiner further states the following:

> The variables vary extensively and when taken as a whole result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the complication in understanding the claimed subject matter impose a serious burden on any examination of the claimed subject matter.

Applicants respectfully submit that the above argument is misplaced. The standard for unity of invention is embodied in PCT Rule 13, stating that the requirement is fulfilled when "there is a technical relationship among those inventions involving one or more of the same or corresponding technical features." Applicants have satisfied the unity of invention standard for the reasons stated above. The Examiner's arguments with respect to the "vastness of the claimed subject matter" and "the variables vary extensively" are inapposite to the unity of invention standard. As stated in M.P.E.P. Appendix AI, Administrative Instructions Under the PCT, Annex B, (f)(iv): the "fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be a justification for a finding of a lack of unity of invention."

Applicants further submit that it is improper for the Examiner to require restriction between the compound/pharmaceutical composition claims, Claims 1 to 21, and the method of treatment claims, Claims 22 to 24. The special technical feature common to all the claims is the significant common chemical structure embodied in Formula I, which all the compounds share. Claims to a class of compounds represented by a Markush group having a common structural moiety that constitutes a special technical feature and methods of using that class of compounds, although belonging to different categories of claims, are clearly within the purview of C.F.R. § 1.475 (b)(2).

At page 7 of the Official Action, the Examiner states the following:

> ... even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn to

> only one of the following combinations: ..... Moreover, according to 37 CFR 1.475(c), If an application contains more or less that one of the combinations of categories of invention set forth in paragraph (b), unity might not be present. In the instant case the claims are drawn to more than one product, process, and method of use.

Applicants submit that the Examiner's reading of 37 C.F.R. § 1.475 is improper. 37 C.F.R. §§ 1.475 (b) and § 1.475 (c) do not constitute a separate standard of unity of invention independent of 37 C.F.R. § 1.475(a). As stated in M.P.E.P. § 1893.03(d): "37 CFR 1.475 was amended effective May 1,1993 to correspond to PCT Rule 13." Furthermore, 37 C.F.R. § 1.475(c) states only that "unity of invention might not be present. (emphasis added)" In the instant case, there is a special technical feature common to Claims 1 to 24 as described above. Claims to a class of compounds represented by a Markush group having a common structural moiety that constitutes a special technical feature and methods of using that class of compounds, although belonging to different categories of claims, are clearly within the purview of C.F.R. § 1.475 (b)(2). Unity of invention exists with respect to Claims 1 to 24 under PCT Rule 13 and 37 C.F.R. § 1.475.

In addition, Applicants refer the Examiner to M.P.E.P. § 821.04, which reads in part:

> However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Thus, even if the Examiner disagrees with Applicants regarding restriction between the compound/pharmaceutical composition claims, Claims 1 to 21, and the method of treatment claims, Claims 22 to 24, the Examiner is required to rejoin any withdrawn method of treatment claims which depend from allowable compound/pharmaceutical composition claims pursuant to M.P.E.P. § 821.04.

Applicants respectfully request reconsideration and withdrawal of the requirement for restriction. Applicants submit that the application is in condition for allowance and passage thereto is earnestly requested. This response is accompanied by a petition for a one-month extension of time. The extension fee set forth in 37 CFR § 1.17(a) as well as any additional fees required in connection with this response may be taken from Merck Deposit Account No. 13-2755. The Examiner is invited to contact the undersigned attorney at the telephone number provided below if such would advance the prosecution of the case.

Respectfully submitted,

By _____

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(732) 594-0182

Date: October 20, 2006

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By _____ Date 10/20/06